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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,471	08/18/2000	Carol M. Kinoshita	10278-017001	6615

7590

12/07/2001

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**Application No.  
**09/641,471**Applicant(s)  
**Kinoshita et al.**Examiner  
**Elizabeth Slobodyansky**Group Art Unit  
**1652**☒ Responsive to communication(s) filed on Oct 30, 2000☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**☒ Claim(s) 81-183 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.☐ Claim(s) \_\_\_\_\_ is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☒ Claims 81-183 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The preliminary amendment filed October 30, 2000 canceling claims 1-80 and adding claims 105-183 has been entered.

Claims 81-183 are pending.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 81-104, drawn to a method of purifying a high mannose glucocerebrosidase (hmGCB), classified in class 530, subclass 412.
- II. Claims 105-171, drawn to a method of producing hmGCB, classified in class 435, subclass 41.
- III. Claims 172-182, drawn to hmGCB preparation, classified in class 435, subclass 201.
- IV. Claim 183, drawn to a method of treating a subject, classified in class 424, subclass 94.61.

The inventions are distinct, each from the other because of the following reasons:

Inventions III and (I, II and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

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(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a hmGCB of invention III can be used in an *in vivo* method of treating a subject of invention IV and in the *in vitro* production of a purified enzyme by a method of invention I.

Inventions I, II and IV are patentably distinct because they are directed to materially different methods. Methods of invention II employ a recombinant cell while methods of invention I employ chromatographic resins and a hmGCB preparation. Methods of inventions I and II are *in vitro* methods that are patentably distinct from an *in vivo* method of invention IV. Methods of inventions I, II and IV use different protocols and chemicals and have different utility.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

A telephone call was made to Ms. Laurie Lawrence on November 19, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

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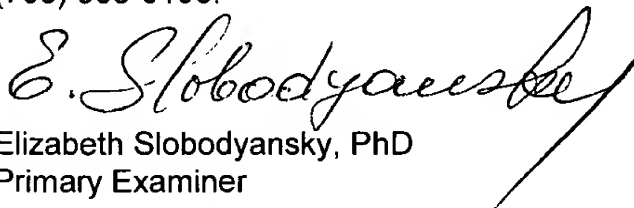
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

  
Elizabeth Slobodyansky, PhD  
Primary Examiner

December 3, 2001